UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Master File No. 01-12257-PBS
	)	Subcategory Case No. 06-11337 -PBS
THIS DOCUMENT RELATES TO:	)	
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., Civil Action No. 06-11337-PBS	)	Hon. Patti B. Saris Magistrate Judge Marianne B. Bowler

UNITED STATES' SURREPLY IN OPPOSITION TO ABBOTT LABORATORIES' MOTION *IN LIMINE* TO EXCLUDE CERTAIN OPINIONS PROFFERED BY PLAINTIFFS' EXPERT MARK G. DUGGAN, PH.D.

TABLE OF CONTENTS

I. Introduction

Dr. Duggan, a highly qualified, empirically oriented economist, has affirmatively demonstrated the numerous steps he took to calculate a reliable estimate of damages, thereby satisfying the United States' burden on a *Daubert* motion. His careful study and comparison of the entire universe of data, together with his use of an extremely large sample representing two-thirds of all claims, resulted in a reliable estimate of the damage caused by Abbott's megaspreads.

Abbott's repeated claims that it has "demonstrated" the unreliability of Dr. Duggan's methods are plainly wrong. Abbott's experts testified that, at Abbott's direction, they never attempted any calculations regarding Dr. Duggan's extrapolations. Young Deposition Transcript Excerpts attached as Exhibit 10 at 215:9-217:9; 221:9-12; 298:17-21 (actually testing the impact "was not included in the scope of my work"); 315:5-8; 423:14-18; 425:13-426:3; Hughes Deposition Transcript Excerpts attached as Exhibit 11 at 599:14-22; 607:12-608:21 ("I wasn't directed to do that."). Abbott also studiously ignores that Dr. Duggan has addressed and accounted for the theoretical concerns which it has raised.[1] Without the support of substantive quantified analysis affirmatively establishing the materiality of the hypotheses it raises, Abbott's arguments are a pale shadow of those required to support a successful *Daubert* challenge such as was done in *Reynolds v. Giuliani*, 118 F.Supp2d 352 (S.D.N.Y. 2000) where the plaintiffs had "thoroughly undermined the structural underpinnings" of the audit, or in *Loughren v.*

[1] Abbott ignores that its criticisms are addressed by Dr. Duggan, but in a different manner than called for by Abbott's experts. Abbott incorrectly equates that to not being addressed. For example, Abbott is fond of claiming that Dr. Duggan failed to account for MACs. Abbott Reply, p. 4. However, Dr. Duggan clearly accounted for MACs when he calculated overall averages, which necessarily included MAC based reimbursement. Abbott's current brief even cites Dr. Duggan's explicit discussion of the impact of MACs in connection with Ohio, Abbott Reply, p. 6, demonstrating Abbott's misleading characterization of Dr. Duggan's work.

UnumProvident Corp., 604 F.Supp.2d 259, 269 (D. Mass. 2009) where the defendant's expert presented "convincing evidence that the technique is susceptible to manipulation and significant error."

II. Dr. Duggan's Methodology Is Not Undermined Through a Few Selected Counter Examples

The First Circuit Court of Appeals' recent AWP decision makes clear that an unsupported assault on damage calculations may properly be rejected. *Blue Cross & Blue Shield v. AstraZeneca Pharms. LP (In re Pharm. Indus. Average Wholesale Price Litig.*), 582 F.3d 156, 198 (1st Cir. Mass. 2009)(Astrazeneca's claims that some payors did not rely on AWP did not render "Dr. Hartman's damages calculation legally infirm.") The damage award in that case was left undisturbed on appeal despite "potential imprecision in the aggregate damages methodology" even in the face of Astrazeneca's allegations regarding the impact of unbilled or uncollected co-payments. 582 F.3d at 198-199. Abbott's attack on Dr. Duggan's work suffers from the same flaws and must be similarly disregarded.

A. Abbott's Cherry-Picked Examples are Misleading

The primary weakness in Abbott's "analysis" can be observed by consideration of a characteristic extrapolation calculation. In order to extrapolate damages from any sample to the remainder of the universe, the key step is to calculate the percent of damages found in the sample. If 80 percent of the dollar value of the sample represents damages, the dollar value of the entire universe is then multiplied by 80 percent to extrapolate the remaining damages.[2] The validity of the extrapolation cannot be tested by cherry-picking an accurate claim from the universe at large to show that extrapolating an 80 percent fraud rate to that particular non-false

[2] An alternative approach with the same result is to calculate the average fraud for each of the sample claims and then multiply that figure by the number of claims in the entire universe.

claim would be wrong. If extrapolations were held to that standard as urged by Abbott, then every extrapolation ever performed would fail. The correct way to analyze an extrapolation is to consider the overall makeup of the sample and the universe, as has been done by Dr. Duggan, but not by Abbott's experts.

B. Convincing Evidence of Error Requires Actual Computations, Not Cherry Picked Counter Examples

A more pertinent challenge to a sample, for instance, was mounted by the plaintiff in *Reynolds*. In that case, the plaintiff successfully challenged the nature of the sample using a quantified and completed analysis of the entire universe, not by brandishing "symptomatic" (i.e. cherry-picked) examples. The primary issue in that case was whether New York was pressuring applicants to withdraw their benefit applications during their first visit to a job center. In order to support its defense, the state used a sample in which only 0.8 percent of the applications had been "withdrawn." However, the plaintiff proved, using another database (which was more complete because it included data which had been overwritten in the database used by the state) that up to 27.8 percent of applicants withdrew their applications at an early stage, rather than the 0.8 percent claimed by the state.[3] Thus, rather than just raising the theoretical possibility that the sample was biased, the plaintiff actually proved that the full universe contained withdrawn applications at 28 times the rate of the sample.

Abbott has made no similar showing, but instead has made the strategic litigation decision to simply raise theoretical concerns without showing them to be meritorious, and then arguing that Dr. Duggan was required to have preemptively disproved each of those theoretical

[3] The plaintiff in *Reynolds* also had its own expert perform chi-square testing (which found that the results did not pass the test at any level of significance, id. at 34) and a binomial test of statistical significance (finding that the chance was less than one in a thousand that the disparity occurred by chance, id. at 31) to further support its critique.

concerns. Abbott's unproven counter arguments carry little weight in the face of the substantial showing put forth by Dr. Duggan, and Abbott has not "demonstrated" that what was done by Dr. Duggan is so inadequate as to require exclusion under *Daubert*.

C. Abbott's Cries of Data Spoliation are Speculative

Although Abbott blows its spoliation horn once again, it does not actually have any evidence of spoliation.[4] Abbott simply argues that because not every bit of evidence in this 11 year, 50+ program fraud scheme was located it must have been spoliated. Further, critically, Abbott's claim, for which it cites no record support, that the United States asserted privilege over the "array gathering" process is false. Abbott participated in depositions of carriers that had produced some, but not all, arrays and pursued questions regarding the nature of the document search and was told other arrays might be in storage, not that they were spoliated.[5] The United States has further exposed the weakness and irrelevance of that claim in its briefing on spoliation.

D. Abbott's Examples Regarding Ingredient Costs are Misleading

Abbott's Reply argues that the variability among the three million Medicaid claims is too great to allow for reliable extrapolation. But Abbott's argument is based merely on the differences among seven single claims. Specifically, Abbott compares the allowed amounts on

---

[4] Abbott has had state produced Medicaid claims data from 30 states in its possession for quite some time, and was awarded an extra year of discovery to secure even more of the data it now claims is so critical. Nonetheless, Abbott made little attempt to secure additional state Medicaid data or information concerning alleged spoliation of state Medicaid data. Similarly, even though it had every opportunity in discovery to seek out the arrays and take testimony concerning their location or dispositions, Abbott failed to depose most of the carriers, or obtain testimony about so-called spoliation of the arrays.

[5] *See, e.g.*, Deposition of First Coast Service Options attached as Exhibit 12 at 59:21-60:06, in response to a question from Abbott counsel regarding whether there were arrays from 1991 to 1994, "I'm not saying there aren't any, but they were possibly in storage. We didn't pull everything out of storage." Similar questions were posed by government counsel, *see also, id.* at 163:16 to 163:21 ("I don't think everything was pulled out of storage" and "the documents said if it was unduly burdensome, don't pull them or don't search, something to that effect.")

single claims for a single NDC for a single year in four of the 10 states to the allowed amounts paid on single claims in three of the 38 states. Abbott Reply, p. 5. In sum, Abbott lines up a total of seven cherry-picked claims for one NDC from a single year, and then leaps to the extreme conclusion that "[t]his type of variability is fatal to" Dr. Duggan's damage calculations.[6]

The irony of Abbott's attempting to prove bias in Dr. Duggan's samples through biased examples is conspicuous, as are the weaknesses in Abbott's examples. Abbott has not shown, for example, that it did not just pick the seven most extreme examples among the three million claims.[7] In a footnote, Abbott states that the examples are "representative" of the per unit reimbursement of each state, but offers no support or explanation as to what that means. One might reasonably expect that Abbott calculated an average price to justify that representation, but limiting the analysis to a state by state peek at seven of 48 jurisdictions for one NDC makes little sense. A more appropriate comparison would be between the average for the 10 states and the average for the 38, *just like Dr. Duggan did for all 44 NDCs*. Duggan Expert Report ("Duggan Expert Rep.")(Abbott Ex. DT), p.78-79; Duggan Rebuttal Report ("Duggan Rebutt. Rep.")(Abbott Ex. DW), p. 12-14.

Likewise, the average reimbursement calculated by Dr. Duggan necessarily included the impact of the MACs claimed by Abbott to be the root of the problem. Dr. Duggan accounted for MACs by calculating the average of *all* claims and he performed his most detailed analysis on the claims from 1999 to 2001 when one would expect the impact of MACs to be at its greatest

---

[6] Additionally, although Abbott relies heavily upon enhanced dispensing fees, none of the seven cherry-picked examples was paid on that basis.

[7] Indeed, Abbott fails to even identify where these examples came from, who selected them, how they were selected, if they are even accurately pulled from relevant data or that it followed any statistical methodology whatsoever. Also, one of the examples is allegedly drawn from Ohio which has been completely dropped from the government's calculations.

since the use of MACs increased over time. Duggan Expert Rep., p. 78 fn. 45; Duggan Rebutt. Rep., p. 12-14. Dr. Duggan's review of the average amounts paid showed that the differences were inconsequential. *Id.* In sum, Dr. Duggan has dealt with this issue sufficiently to satisfy the United States' burden and Abbott's cherry-picked counter examples do not demonstrate otherwise.

E. Abbott's Examples Regarding Enhanced Dispensing Fees Are Misleading

Abbott's Reply also argues that Dr. Duggan's sample is biased because the 15 "enhanced dispensing fee" states represent 40 percent of the 38 states, double the 20 percent represented by the 2 "enhanced dispensing fee" states among the 10 sample states. The United States has previously explained why Abbott has failed to demonstrate any actual difference between the 10 and the 38 states. United States Opposition to Abbott Motion in Limine ("U.S. Opp. Memo"), Dkt. 6600/500, at 22 to 24. Several weaknesses were demonstrated in Abbott's dispensing fee claims[8] and a closer look will further illustrate this.

First, it should be noted there are at most 14 states at issue, not 15, because Abbott has counted Ohio among the 15 even though Ohio has been completely dropped from the United States damage analysis and is therefore irrelevant to this issue.

[8] Abbott's corresponding theory that the enhanced dispensing fees were an ineluctable outcome of the "drastic" reduction in ingredient cost incorporated in Dr. Duggan's model has no empirical support. In mid-2001, Abbott voluntarily reported lower prices causing Abbott's AWP spreads to drop from an average of 1,000 percent in 2001Q2 to an average of about 80 percent in 2001Q3. This real life example, cited by Dr. Duggan, Duggan Rebutt. Rep., p. 4-5, gave rise to no change in utilization, no increased dispensing fees, no loss of access to Medicaid and no pharmacies going out of business. *See also*, Young Expert Report, Abbott Motion in Limine Exhibit D, p. 34 (Abbott's unit sales in 2002 were higher than in 2001). Moreover, Abbott representatives have unequivocally testified that its price setting and reporting behavior was never in any way dependent upon a desire by Abbott to compensate for any dispensing fee shortfalls for providers. Sellers 30b6, 3/31/08 at 347-348; 350-351; 606-609. (Lavine Decl. Exh. 89, Dkt. 6312-25/324-15)

Second, many of the 14 states are low utilization states. The 14 states only represent 27 percent of the extrapolated damages, not 40 percent. Five of the supposed 14 "enhanced dispensing fee" states in combinations add up to less than $135,000 out of $21,000,000 (.64 percent) in extrapolated damages.[9]

Third, the enhanced fees are paid for drugs that require compounding or are administered intravenously by the billing provider, not simply on the basis of their claimed status of what Abbott describes but never defines as "IV" drugs.[10] Abbott has made no actual showing of how many of the claims for its drugs were impacted by the compounding or IV issue (or if claims billed under those special rules are even contained in the data). For example, Abbott has never demonstrated the frequency with which its products are compounded as compared to being used for a simple admixture or for irrigation.

Fourth, Abbott has never accounted for whether or not the Abbott customers submitting these claims secured additional compensation pursuant to claims submitted for associated services under home health care benefits, long term care benefits, hospice benefits, durable medical equipment benefits, etc. If so, Abbott's theory that those customers required, deserved or received enhanced dispensing fees is suspect.

Finally, Abbott exaggerates the scope and magnitude of the enhanced dispensing fees.

---

[9] For example, the *total* damages for Washington, D.C. (counted as one of the 38 states) are $17,000.00. The damages for Alaska are less than $20,000.00. Idaho is less than $33,000.00. Vermont and New Hampshire are both under $38,000.00. Duggan Suppl. Report, Tables 27A and 27B.

[10] These are significant issues. Compounding fees are not appropriate for simple admixtures. *See, e.g.*, Dubberly Deposition Transcript Excerpts attached as Exhibit 6 to U.S. Opp. Memo. Also, several of the Abbott drugs at issue are for "irrigation" and therefore not used for compounding. Several other drugs are marketed as "Add-Vantage" products, which is a system in which "drugs can be prepared **in seconds** without needles, syringes or alcohol swabs" apparently vitiating the need for enhanced dispensing fees. See Excerpts of Abbott 2001 Catalog attached as Exhibit 13 (emphasis added).

As noted in the U.S. Opposition Memorandum, p. 22, Abbott highlights the enhanced fees of four states, Maryland, Minnesota, Nevada and Utah, but ignores the other 10 states, and a closer look explains why. Most are so trifling that the odds of their having any material impact is negligible (and Abbott has not taken any steps to show otherwise).

The "enhancement" of six of the other 10 states was ***a dollar or less***,[11] and the other four are similarly limited in nature. For example, Vermont did not pay any extra for compounded prescriptions during the operative period of this case.[12] Pennsylvania and West Virginia paid only one extra dollar for compounded drugs, as did Maine in limited circumstances, and Idaho for unit drug doses. Washington, D.C. paid one extra dollar for compounded drugs for only four relevant years, 1991 to 1995. Alaska paid up to $10.00 and New Hampshire paid $4.50 per 15 minutes as dispensing fees, but total damages from 1991 to 2001 are only $19,636 and $37,783 respectively, making their dispensing fees immaterial. In 1996, the State of Washington eliminated its modest compounding fee ($1.16 or $1.30 per 5 minutes for compounding time, even less than New Hampshire). Finally, although South Carolina allowed long term care facilities to opt to be reimbursed under an Alternate Reimbursement Methodology (ARM) Abbott has not shown that compounded claims for its drugs processed under this special rule

---

[11] The impact of an extra dollar dispensing fee is *de minimus*. Consider a claim actually paid on the basis of an inflated ingredient cost of $10 (instead of non-inflated $2), plus a dispensing fee of $4 for a total of $14. In states with an extra dollar dispensing fee, Abbott's unstated point seems to be that Dr. Duggan should have calculated the fraud ratio as $8 over $15, rather than $8 over $14. The ratio would then have been 53.3 percent, not 57 percent for the small dollars at issue in those states. For vancomycin, which alone represents almost 40 percent of total Medicaid utilization, Duggan Rep. Table 11, the difference would be along the lines of $60/66 versus $60/67, or 90.9 percent v. 89.5 percent. These modest differences mostly found in low utilization states would be further diluted when spreading the impact across all of the states as is appropriate.

[12] A separate chart containing a detailed recitation of the reimbursement methodology of each state is contained in Henderson Common Ex. ("HC Ex.") 24.

were included in the data or the amount of any extra reimbursement.

The foregoing look at the 10 other so-called "enhanced dispensing fee" states demonstrates yet again why Abbott's inchoate analyses are unhelpful, and why Abbott specifically relied only upon the other four states - Maryland, Minnesota,[13] Nevada and Utah. In addition, as noted in the United States' opposition brief, Utah did not implement an extra payment for compounding until 2001 thereby affecting virtually none of the extrapolation. Even Maryland and Minnesota paid only a modestly "enhanced" fee in the range of an extra $3.00 to $4.00. The last state, Nevada, representing 1.3 percent of extrapolated damages, paid ***only*** **home health companies and nursing facilities**[14] a dispensing fee of $11.20 or $16.80 **only** on the first "**medicine**" (i.e., not water) administered intravenously. In combination, Maryland, Minnesota and Nevada represent only 6.3 percent of the total extrapolated damages. In comparison, Michigan and Wisconsin (the 2 states among the 10 with enhanced fees) paid from $10.00 up to $40.11 for compounded prescriptions and represented 20 percent of the weight of the extrapolation.

F. The Sharing of Arrays among Carriers Strengthens Dr. Duggan's Analysis

Abbott's suggestion that some negative consequence should flow from the sharing of arrays among carriers is illogical. Abbott does not dispute the relevant point that the arrays were *used* by 21 carriers. Plus, if anything, the sharing of arrays reduced the impact of the variability upon which Abbott rests much of its argument. Indeed, Abbott disingenuously mixes apples and

---

[13] Abbott also fails to explain why a state would implement an enhanced dispensing fee for compounded drugs and simultaneously embrace continued spread based payments purposely left in the control of the drug companies.

[14] Notably, those facilities potentially collected spread not only on Abbott's fluids, but also on expensive, high spread ingredient drugs infused using Abbott's solutions – including, for example, Remicade and vancomycin.

oranges by comparing the number of Part B carriers who actually created arrays (as opposed to the number of carriers who actually used those arrays) to the total number of Part B carrier codes. While Dr. Duggan calculated damages with respect to claims of 90 carrier codes, Table 35 of his report plainly shows that numerous codes relate to the same carrier, and that, in fact, there are approximately 44 distinct Part B carriers. Finally, Abbott disregards entirely the fact that Dr. Duggan reasonably tested whether the arrays that he did have were representative of the total population and made appropriate adjustments. Specifically, Dr. Duggan determined the frequency with which each of the two groups had an Abbott NDC's AWP (or 95 percent of its AWP) as the allowed amount per unit. Dr. Duggan found that the carriers for which he lacked arrays used the Abbott AWP as the allowed amount somewhat less frequently than the carriers for which he had arrays (18.44 percent versus 24.41 percent), and he adjusted his damage calculations downward to account for this.

III. Conclusion

Based upon the foregoing, and its arguments set forth in its Opposition to Abbott's Motion in Limine, and given Abbott's utter failure to prepare alternative calculations and actual quantified testing of Dr. Duggan's analysis, Abbott's assault on Dr. Duggan's work product is unpersuasive. Accordingly, the United States respectfully requests that this Court deny Abbott's Motion In Limine, admit Dr. Duggan as a qualified expert, and deny Abbott's motion for summary judgment pertaining to damages.

Respectfully Submitted,

For the United States of America,

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

/s George Henderson
George B. Henderson, II
Assistant U.S. Attorney
John Joseph Moakley U.S. Courthouse
Suite 9200, 1 Courthouse Way
Boston, MA 02210
Phone: (617) 748-3272
Fax: (617) 748-3871

JEFFREY H. SLOMAN
ACTING UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF FLORIDA

/s Mark Lavine
Mark A. Lavine
Ann St.Peter-Griffith
Special Attorneys for the Attorney General
99 N.E. 4th Street, 3rd Floor
Miami, FL 33132
Phone: (305) 961-9003
Fax: (305) 536-4101

TONY WEST
ASSISTANT ATTORNEY GENERAL

Joyce R. Branda
Daniel R. Anderson
Renée Brooker
Justin Draycott
Rebecca Ford
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
Phone: (202) 305-9300
Fax: (202) 616-3085

For the relator, Ven-A-Care of the Florida Keys, Inc.,

/s James Breen
James J. Breen
Alison W. Simon
The Breen Law Firm, P.A.
3350 S.W. 148th Avenue, Suite 110
Miramar, FL 33027
Phone: (954) 874-1635
Fax: (954) 874-1705

November 16, 2009

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "UNITED STATES' SURREPLY IN OPPOSITION TO ABBOTT LABORATORIES' MOTION *IN LIMINE* TO EXCLUDE CERTAIN OPINIONS PROFFERED BY PLAINTIFFS' EXPERT MARK G. DUGGAN, PH.D." to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ Mark Lavine

Dated: November 16, 2009